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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

April 12, 2000

WARNING LETTER

Ref: 2000-DAL-WL-08

VIA FEDERAL EXPRESS

Mr. Paul R. Judia, President
Galveston Medical Supplies, Inc.
711 25th Street
Galveston, Texas 77550

Dear Mr. Judia:

During a February 29 and March 1, 2000, inspection of your home respiratory care and medical gas repacking operation, an investigator from the Food and Drug Administration documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations. These deviations cause the medical oxygen repacked at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Specifically, the drug product, Liquid Oxygen U.S.P., is adulterated in that your firm has failed to maintain the methods, facilities, and controls for processing, packaging, and holding of this drug in conformance with Current Good Manufacturing Practice Regulations as prescribed by Title 21, Code of Federal Regulations, Parts 210 and 211, such as:

1. Failure to assay the incoming liquid oxygen for identity and strength prior to filling the liquid home units [21 CFR 211.165(a)].

2. Failure to assay cryogenic home vessels for identity and strength after being filled with liquid oxygen U.S.P. [21 CFR 211.165(a)].

3. Failure to establish master production records that include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.186(b)].

4. Failure to maintain batch production records that include documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)].

5. Failure to establish responsibilities and procedures for the quality control unit to have responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products, and authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated [21 CFR 211.22(a) and 21 CFR 211.192].

6. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch [21 CFR 211.130(b)].

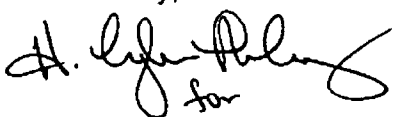
The above is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,



for

Michael A. Chappell
District Director